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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,069	07/09/2004	Gerard Moinet	MERCK-2900	3108

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EXAMINER	
ZHANG, NANCY L	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/501,069	MOINET ET AL.	
	Examiner	Art Unit	
	Nancy L. Zhang	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *12-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I, claims 1-11, in the reply filed on 7/7/2006 is acknowledged. The traversal is on the ground that in the last Office Action there was no proof provided for requirements set forth in MPEP §806.05(h) for restriction requirement. This is not found persuasive because MPEP §806.05(h) applies only for applications filed under 35 U.S.C. 111 whereas the instant application was filed under 35 U.S.C. 371.

Applicant's election without traverse of species (A) wherein the composition comprises pioglitazone as the glitazone and 2-benzyl-4-(4-fluorophenyl)-4-oxobutanoic acid as the compound of formula (I) is also acknowledged. Applicant's remarks made on the species election requirement have been considered and are not found persuasive. The Office views that there is no shared special technical feature (among the species which are combinations of two different compounds) because different compounds and different enantiomers have different properties. For example, there is no special technical feature shared between a combination of pioglitazone and 2-benzyl-4-(4-fluorophenyl)-4-oxobutanoic acid and a combination of KRP297 and 2-(b-naphthylmethyl)-4-phenyl-4-oxobutanoic acid.

The restriction requirement is still deemed proper and is therefore made FINAL.

Claims 12-19 are withdrawn from consideration because they are directed to the non-elected invention.

Claims 1-11 are examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 6 recites the broad recitation "from 10^{-3} to 40", and the claim also recites "from 10^{-3} to 10" which is the narrower statement of the range and then the claim further recites "from 10^{-3} to 1" which is the even narrower statement of the range.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitcomb (US Patent 6,011,049, issue date: Jan. 4, 2000) in view of Moinet (WO 98/07681, publication date: Feb. 26, 1998).

Claims 1-11 recite a pharmaceutical composition comprising one glitazone of formula (II) and a compound of formula (I). Claims 3-5 limit that the composition is for treating diabetes such as non-insulin-dependent diabetes and pathologies associated with insulin resistance syndrome. Claim 6 limits that the weight ratio between the

glitazone and the compound ranges from 10^{-3}:1 to 40:1. Claim 11 limits that the composition is suitable for oral administration.

Whitcomb discloses a composition for the treatment of non-insulin dependent diabetes (column 17, line 4) comprising 5-2500 mg of a glitazone antidiabetic agent. Pioglitazone is one of the glitazone agents in Whitcomb's composition (column 16, lines 65-67). The composition is useful for treating diabetes and associated complications (column 1, lines 37-39). Whitcomb also discloses that the composition is normally made for oral administration. Whitcomb does not teach the compound of formula (I) being included in the composition. However, a compound of formula (I) such as 2-benzyl-4-(4-fluorophenyl)-4-oxobutanoic acid is known in the art (Moinet, column 2, line 2) as being used in pharmaceutical compositions for treating diabetes (Moinet, column 1, line 3).

In re Kerkhoven (205 USPQ 1069, CCPA 1980) states that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose: the idea of combining them flows logically from their having been individually taught in the prior." Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine pioglitazone and 2-benzyl-4-(4-fluorophenyl)-4-oxobutanoic acid in a 1:1 ratio in a pharmaceutical composition, motivated by their having been taught by the prior art to be useful in treating diabetes, consonant with the reasoning of the cited case law.

Therefore, the claimed invention as a whole was prima facie obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy L. Zhang whose telephone number is (571)-272-8270. The examiner can normally be reached on Mon.- Fri. 8:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

8/31/06

NLZ

9/3/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER